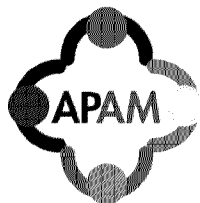


# PSJ3

## Exhibit 422



## Alliance to Prevent the Abuse of Medicines

### Alliance Background

The Alliance to Prevent the Abuse of Medicines – launched in the fall of 2013 and comprised of its members the **American Medical Association, Cardinal Health, CVS Caremark, the Healthcare Distribution Management Association (HDMA), Prime Therapeutics, and Teva Pharmaceuticals** – has been working to put forth achievable solutions, and serve as a resource for policymakers and the media.

The members of the Alliance are among the biggest organizations in their respective industries, and each represents a key function in the pharmaceutical supply chain from manufacturer, to distributor, pharmacy benefit managers, to dispenser, to providers. As the only coalition focused on this issue that includes representation across the domestic pharmaceutical supply chain, the Alliance brings a comprehensive perspective to addressing the prevalence of prescription drug abuse, and seeks to overcome piecemeal approaches to the problem that may not result in the intended impact.

The members of the Alliance believe that the diversion and abuse of prescription drugs is a national, public health crisis that must be confronted and addressed through a collaborative effort by all stakeholders via a multi-faceted approach that includes education, disposal, monitoring, and treatment. This diversion and abuse can tragically deprive those who legitimately need medicines from access to quality care, and threaten the welfare and health of those afflicted by abuse, as well as those associated with them.

Since its inception, the Alliance members have convened routinely to discuss the most comprehensive and effective public policy solutions to address the growing problem of prescription drug diversion and abuse. These discussions have confirmed that there is no silver bullet for addressing this health crisis. But rather the Alliance has identified seven (7) policy concepts outlined below that if pursued would have a significant mitigating effect on diversion and abuse.

### ***Findings -- The Alliance finds that prescription drug abuse is an epidemic in the United States warranting a strong public health response.***

- A June 2011 Institute of Medicine report found that one hundred million American adults are burdened with chronic pain. It is essential that prescription medicines that provide relief are accessible to those in need. However, the U.S. Centers for Disease Control & Prevention warns on its website that the abuse of prescription medicines a “growing, deadly epidemic.”
- The CDC reports also that the inappropriate use of prescription pain relievers is responsible for 475,000 emergency department visits annually, and that more than 6 million Americans

suffer from prescription drug abuse – roughly one in 20 people in the U.S. reported using prescription painkillers for non-medical reasons in the past year.

- While nearly every state (49) has a prescription Drug Monitoring Program (PDMP) to help identify abusers within the health care system, these programs vary dramatically in funding, use, and capability.
- The National Survey on Drug Use and Health (NSDUH) published in April 2011 shows that nearly one-third of people aged 12 and over who used drugs for the first time in 2009 began by using a prescription drug non-medically.
- An April 2012 Journal of the American Medical Association (JAMA) study found that 3.4 of every 1,000 infants born in 2009 suffered from neonatal abstinence syndrome (NAS) (i.e., withdrawal symptoms) – at a rate of one every hour.
- As cited in the October 2013 Issue Report from Trust for America's Health, a study conducted in 2011 reflected the following costs in 2006 related to prescription drug abuse: \$42 billion in lost productivity; \$8.2 billion in increased criminal justice costs; \$2.2 billion for drug abuse treatment; \$944 million in medical complications. The total cost to the system due to prescription drug abuse was \$53.4 billion dollars in 2006.

### **Prescription Drug Abuse Legislative Concepts**

#### **I. Public Health Approach -- *The Alliance supports a public health approach to preventing the abuse of medicines by placing a premium on prevention, early identification of abuse, and treatment through promotion of public health tools such as widespread adoption of drug courts and Medicaid adoption of prescription drug abuse screening tools coverage, such as SBIRT, or other patient intervention and treatment approach.***

- Expansion of national and community-based prescription drug abuse prevention programs in schools, communities and the workplace.
- Ensure and evaluate access to coverage of prescription drug abuse treatment by insurers, exchanges, Medicaid and Medicare to cover treatment for prescription drug abuse and addiction per Mental Health Parity Act and Affordable Care Act requirements.
- Target and expand funding and resources to prescription drug abuse prevention and treatment (the President's FY 2014 Budget includes an increase of \$1.4 billion for treatment over the FY 2012 amount).
- Department of Justice to conduct an analysis of states where drug courts have been successful, and then establish a federal plan, which implements identified best practices nationwide so states can adopt.
- Department of Justice to fund a study to assess the effectiveness of drug courts in decreasing prescription drug abuse and lowering costs associated with prosecution and incarceration.
- Coordinate the law enforcement associated with drug courts with federal and state prescription drug treatment programs to improve likelihood of early intervention and rehabilitation.
- Expansion of Screening, Brief Intervention, and Referral to Treatment Coverage (SBIRT), or similar patient treatment approach, as an intervention protocol for early prevention and treatment at all places of patient care.

- Encourage HHS, with NIDA, NIH, NIAAA, and SAMHSA, to conduct research regarding the effectiveness of applying the SBIRT model to substance misuse/abuse (currently utilized predominantly for alcohol and tobacco)
- HHS to target seven states where prescription drug abuse is prevalent and to provide grant dollars to those states to train health care professionals in early detection and treatment of prescription drug abuse.
- Establish health care provider (primary care centers, hospital emergency rooms, trauma centers, community health care settings) reimbursement codes for adoption in all 50 states. To date, only 19 states have adopted.
- HHS to provide grants to states to ensure national coverage of SBIRT, or similar patient intervention and treatment program.
- HHS to provide communication to providers of the availability of non-Medicaid reimbursement for SBIRT, or similar patient intervention treatment program.
- Require Medicaid coverage of treatment for patients referred through SBIRT or similar patient intervention program, including access to specialty care.

**II. Improve the Effectiveness of Prescription Drug Monitoring Programs (PDMPs) -- *The Alliance believes that each state should operate an effective, interoperable and up-to-date PDMP that is integrated into physician and pharmacist workflow.***

- The Alliance supports a Government Accountability Office (GAO) study to evaluate research-based evidence that demonstrates PDMP effectiveness, relating to the various characteristics of PDMPs (daily data collection/reporting and accessibility by physicians and pharmacy information sharing among states, doctor shopping thresholds, PMP staff size, etc.) to outcomes
- Advocate for solutions that provide physicians and pharmacists with patient-specific, daily updated information at the point-of-care for the purpose of improving public health.
- Support full funding and staffing for up-to-date, and interoperable prescription drug monitoring programs at the point-of-care that are integrated into a physician's and pharmacist's workflow.
- Require each state to have an effective interoperable and daily updated Prescription Drug Monitoring Program, which should include integration of PDMP data into electronic health records (EHRs). The PDMP should identify the patient and the provider.
- Establish adoption of National Association of Boards of Pharmacy (NABP) Interconnect program to apply nation-wide and to allow uniform access guidelines across states.

*The Alliance supports the components of a strong prescription drug-monitoring program as set forth by the National Association of Model State Drug Laws (NAMSDL). Effective PDMP components should be as follows:*

- The PDMP would monitor federal controlled substances, additional specified controlled substances regulated by the state, and drugs of concern documented to demonstrate a potential for abuse, particularly those identified by law enforcement and addiction treatment professionals.

- The PDMP would proactively provide data to prescribers, dispensers, law enforcement and occupational licensing individuals.
- The PDMP statute should allow the Administrator to disclose de-identified data for statistical, public research, public policy or educational purposes. Prior to disclosure, the Administrator should remove all information, which identifies, or could reasonably be used to identify, the patient, prescriber, dispenser or other person who is the subject of the information.
- The individuals or officials allowed to request specific data from the program should include prescribers, dispensers, law enforcement and prosecutorial officials, health licensing agencies or boards for prescribers and dispensers, and patients. Also, state officials should include as authorized users those individuals whose use of the information will enhance patient safety and patient care.
- Requestors of PDMP information should demonstrate that they have the education, training or instruction necessary to responsibly and properly use the information that they receive from the program. Designated categories of requestors should be required to prove that they have received education, training or instruction on the purpose and operation of the program, and how to appropriately use the data.
- Health licensing agencies or boards for prescribers and dispensers, by statute, regulation, rule or policy should establish standards and procedures for their licenses regarding access to and use of PDMP data.
- State officials, by statute, regulation, rule or policy, or in practice, should establish an appropriate linkage from the PDMP to addiction treatment professionals to help individuals identified through the PDMP as potentially impaired or potentially addicted to a substance monitored by the PDMP.
- Each state should provide for appropriate interstate sharing of PDMP data by statute, regulation or interstate agreement. Recipients of PDMP data from other states may include prescribers, dispensers, law enforcement representatives, PDMP officials or other specified authorities.
- PDMP data should not be subject to public or open records law. The enabling statute for the PDMP should also include penalties for knowingly disclosing, using or obtaining information other than as authorized by law.
- The PDMP should include an evaluation component that identifies the cost benefits of the PDMP, impacts of the use of the data on the practices of authorized users, any recommended operational improvements and other information relevant to policy, research and education involving controlled substances and drugs of concern monitored by the PDMP. As part of the ongoing assessment process, an advisory committee or designated individuals should provide advice and input regarding the development and operation of the PDMP.

**III. Abuse Deterrent Technology -- *The Alliance supports the Food and Drug Administration (FDA) to require generic versions of extended-release, long acting opioids to have abuse-deterrent properties that are equal in effectiveness, but not necessarily identical to the brand. Abuse deterrent technology is an important and effective tool that should be used to help address prescription drug abuse, and should be incentivized for manufacturers to advance the development of this technology.***

- Require FDA to be the arbiter of what is an effective deterrent.
- FDA to take into account the continued evolution of abuse deterrence technology, and the need for these products to prove abuse deterrence by increasing the safe use of a product and to prevent abusers from being able to “easily circumvent” the protective measures of a product.
- FDA to establish parameters for approval of generic abuse deterrent formulations.
- Require abuse deterrent technology for generic products to be as effective as, but not necessarily identical to, the brand reference product.

**IV. Eliminating Pill Mills -- *The Alliance supports enforcement actions to halt “pill mill” activities through legislation that develops standards for pain management clinics and assists prescribers with guidelines on how to prescribe painkillers safely and effectively.***

- National Association of Boards of Pharmacy to establish guidelines for prescribers on safe and effective prescribing of painkillers.
- HHS to conduct study of best practices in states regarding statutes and guidelines on regulating pain management clinics. Develop state model based on study findings of best practices and encourage states to adopt state model.
- HHS and DEA should work with states legislatures and state departments of health to adopt model state legislation that would include the following elements:
  - Clearly define “pain clinic”, “pain management clinic”, and “chronic pain”
  - Require state certification/registration of pain clinics
  - Require clinic owners to hold certain state licenses/board certifications
  - Require designation of individual to bear certain responsibilities regarding clinic operations and compliance
  - Require certain qualified individuals be present for a certain percentage of clinic operating hours
  - Restrictions on the prescribing/dispensing of controlled substances in a pain clinic setting
  - Requirements with respect to PDMPs
  - Require clinic employees to meet certain qualifications or receive specific training
  - Clinic inspection requirements and/or procedures
  - Require that pain clinics maintain certain records and/or collect certain data
  - Specify administrative and/or criminal penalties for violating pain clinic provisions.

The State of Kentucky serves as a prime example of model state legislation, with the following statutes included in the pill mill law:

- Kentucky defines a pain management clinic as “a facility where the majority of patients of practitioners at the facility are provided treatment for pain that includes the use of controlled substances and: 1. The facility’s primary practice component is the treatment of pain; or 2. The facility advertises in any medium for any type of pain management services...”
- The state only permits a physician having a full and active license to practice medicine shall have an ownership or investment interest in a pain management facility.

- At least one of a clinic's owners or an owner's designee (who is a physician employed by and under the supervision of that owner) must:
  - Hold a current subspecialty certification in pain management or hospice and palliative care by a member board of the American Board of Medical Specialties, or hold a current certificate of added qualification in pain management or hospice and palliative medicine by the American Osteopathic Association Bureau of Osteopathic Specialists; or
  - Hold a current board certification by the American Board of Pain Medicine or the American Board of Interventional Pain Physicians; or
  - Have completed a fellowship in pain medicine or an accredited residency program that included a rotation of at least five months in pain management; or
  - Meet certain qualifications if he was an owner or practiced in that specific pain management facility prior to and continuing through July 20, 2012; or
  - If the facility is operating under a registration filed with the Board of Medical Licensure, have completed or hold, or be making reasonable progress toward completing or holding a certification or training substantially equivalent to the specified certifications.
- The facility shall have a medical director who is board certified and has an unencumbered license to practice.
- The medical director shall be responsible for complying with all requirements related to the licensure and operation of the facility.
- At least one clinic owner or an owner's designee be physically present practicing medicine in the clinic at least 50% of the time that patients are in the facility.
- Each prescriber employed or contracted by a pain management facility shall be board certified and have a full, active license to practice
- The Board of Medical Licensure has authority to obtain Kentucky PMP reports and analyses for each practitioner at a pain management facility.
- At least once per year, the Board of Medical Licensure must obtain a Kentucky PMP review and analysis for each physician who owns, is employed by or practices in a pain management facility.

**V. Education and Training on Prescription Drug Abuse -- *The Alliance supports positive incentives and education for providers, dispensers and authorized handlers of controlled substances to prevent the abuse of medicines. Education for the public – consumers, patients and all stakeholders – is essential to stopping this public health epidemic and helping prevent new cases of abuse.***

- Establish positive incentives to promote physician education, which provide current best prescribing practices and are tailored to meet a physician's practice/patient population needs.
- Establish and fund educational programs for pharmacies to identify potential signs of diversion and abuse when filling prescriptions.
- Require employee training on prescription drug abuse and signs of diversion to create greater awareness and help identify potential issues with employees and customers, including educating administrative employees, sales teams and facility workers.
- Authorize Department of Health and Human Services to conduct nationwide public education campaign on prescription drug abuse.

**VI. Medicaid and Medicare Pharmacy Lock-In Program -- *The Alliance recommends improving State Medicaid pharmacy "Lock-In" programs and establishing a Medicare pharmacy "Lock-In" program as avenues for States and the Medicare program to prevent and fight the abuse of prescription medicines by Medicaid and Medicare Part D beneficiaries.[reference model state legislation, i.e., WA, IA]***

- Require Medicaid programs to establish a "Lock-In" program under which procedures are designed to prevent fraud and abuse in the dispensing of certain controlled substances to high users, including restricting the beneficiary to obtain prescriptions from only one pharmacy and one hospital/emergency room.
- Establish exceptions to Medicaid beneficiaries in areas such as rural regions where access to pharmacies and hospitals is limited.
- Establish a Medicare Part D "Lock-In" program to prevent fraud and abuse in the dispensing of certain controlled substances to high users, including restricting the beneficiary to obtain prescriptions from only one pharmacy and one hospital/emergency room.
- Establish exceptions to Medicare Part D beneficiaries in areas such as rural regions where access to pharmacies and hospitals is limited.

**VII. Enhance Oversight of Controlled Substances and Establish Prescription Drug Abuse Working Group (Marino/Blackburn Bill) -- *The Alliance supports bringing greater clarity to the requirements for the safe and secure distribution and dispensing of controlled substances and establishment of a prescription drug abuse working group to report to Congress.***

- Clarify existing authorities under the Controlled Substances Act (CSA). Implement a process to identify and mitigate concerns pertaining the distribution and dispensing of controlled substances and establish an escalation process prior to revocation or suspension of licenses.

- Require registrants to obtain criminal background checks and drug tests on each employee who has or will have access to controlled substances. Licensed healthcare professionals such as dispensers would be exempted from this section's requirements.
- The bill requires the Attorney General to give the registrant an opportunity to submit a corrective action plan that demonstrates how the registrant plans to correct the grounds for revocation or suspension and for the Attorney General to then determine whether, in light of the plan, revocation or suspension proceedings should be discontinued or deferred.
- Establish a Working Group composed of 20 members, appointed by the President, from such groups as: public policy experts, FDA, ONDCP, patient groups, representatives from pharmacies, prescribers, hospitals, pharmaceutical wholesalers, state Attorneys General, and law enforcement officials.
- The Working Group shall review and report to Congress on Federal initiatives with respect to efforts to reduce prescription drug diversion and abuse; identifying gaps and opportunities with respect to ensuring safe use; examine recommendations for rescheduling products from Schedule III to II and the effectiveness of rescheduling in reducing diversion and abuse, as well as effect on access for legitimate medical purposes; make recommendations on specific ways to reduce the diversion and abuse of prescription drugs.

**VII. Take Back Program Proposal – *The Alliance seeks to decrease the supply of diverted prescription drugs, and, to that end, supports the appropriate removal of unused, unneeded or expired prescription drugs, including controlled substances, from medicine cabinets and out of the reach of potential abusers, and federal funding for a national framework to support accessible state-level Take Back locations. The Alliance puts forth the following guidance to ensure an effective Take Back program under the DEA proposed rule:***

- The requirements of voluntary participation in Take Back should not be prohibitively burdensome with respect to cost, liability, or compliance hurdles, so as to deter participation and therefore limit the usefulness of the program.
- Any proposed rule offered by DEA implementing the drug disposal statute should be harmonized with other federal agency rules (see EPA, OSHA, FDA, DOT), as well as state requirements.
- A proposed DEA rule should ensure expansion of the program to allow for additional federal agencies, e.g., DOD, VA, to participate in the program.
- DEA, in conjunction with other federal agencies participating in the Take Back program, should from time to time study the effectiveness of the program comparative to the prescription drug epidemic to evaluate whether the program is having a mitigating effect. Such evaluation should ensure that the economic and environmental impacts of the program remain minimal.

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